REMARKS

Copies of the Opinions cited below are attached for the Examiner's convenience.

The only independent claim under examination is claim 206, which is:

206. A medical balloon catheter comprising a multilayer balloon having a first extruded layer and a second extruded layer, wherein the first layer comprises a first polymeric material selected from the group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and the second layer comprises a second polymeric material different from the first polymeric material.

This claim stands rejected under the "written description" requirement of 35 USC 112 paragraph 1. The rejection reasons that the claim would be allowable if amended to require that the first layer, of PEEK or PEK, is a tensile layer, and the second layer is an adhesive material or bonding layer. Applicants traverse. This reasoning limits applicant to a preferred embodiment described in the specification, without considering the full teaching of the specification.

It is not necessary that the specification include a literal description of the invention. All that is required is that the specification as a whole convey to a person of ordinary skill in the art that the inventor was in possession of the invention. It may be the case that a specification provides a written description that expressly limits the invention. For example, in Gentry Gallery, Inc. v. Berkline Corp. 134 F.3d 1473 (Fed. Cir. 1998), a case related to a patent directed to a sectional sofa with a console and controls, the court found that claims broad enough to cover locating the controls somewhere besides the console were not supported because the specification identified the console as the only possible location for the controls:

> It is a truism that a claim need not be limited to a preferred embodiment. However, in a given case, the rights to exclude may be limited by a narrow disclosure.
>
> * * * *
>
> In this case, the original disclosure clearly identifies the console as the only possible location for the controls.

Of course, Gentry Gallery, in the quotation above, reiterates the principle that claims can be broader than a preferred embodiment in cases where the specification is not limiting to the preferred embodiment. The analysis is, simply, whether the specification conveys the invention to a person of ordinary skill in the art. For example, the Federal Circuit, in Utter v. Hiraga 845 F.2d 1993 (Fed. Cir. 1988):

> A specification may, within the meaning of 35 U.S.C. §112 p, contain a written description of a broadly claimed invention without describing all of the species that claim encompasses.

If claiming species, then must be supported

In Utter, the invention related to a scroll compressor including a section pivot that could be either an internal pivot or an external pivot. The specification described only an internal pivot, which provided sufficient description of the claimed invention, which was not limited to the location of the pivot. Other instructive cases include In re Rasmussen 6450 F.2d 122 (CCPA 1981) and In re Peters 723 F.2d 1981 (Fed. Cir. 1983).

In this case, the specification is not only not limited to a balloon with an outer tensile layer and an inner adhesive layer, it goes further. The specification expressly describes the concept of a composite balloon made of multiple layers in various combinations to provide user selected combination of properties. For example, the Field, Summary and Abstract of the specification conveys:

> I. Field of the Invention
> This invention relates generally to balloon catheters, and more particularly to a method for fabricating a multiplayer balloon composite exhibiting enhanced characteristics attributable to the properties of the individual layers. (p. 1, L. 1-7)
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> * * * *
>
> The above-listed desirable characteristics are achieved in accordance with the present invention by forming a multi-layer balloon where the individual layers afford a desirable property to the composite. (P. 2, L. 20-23)

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ABSTRACT

A method of producing laminated inflatable, substantially inextensible expander members having composite properties enhancing their use on intravascular catheters, such as angioplasty catheters is described. Diverse polymeric compounds of differing properties are coextruded to create a multiplayer parison. The parison is subsequently drawn and expanded in a blow molding operation to yield an expander member exhibiting enhanced properties including lubricity, burst-strength, limited radial expansion, bondability, and rupture characteristics. (P. 16)

Turning to the description of specific materials including, PEEK and PEK, the specification makes clear they can be used in various combinations:

> Examples of materials exhibiting the required high tensile, low distensibility...including polyetheretherketone (PEEK)... and polyetherketone (PEK), ...
>
> It will be appreciated that the particular combination chosen would depend on the particular application and particular catheter involved, and that an array of multi-layer expanders of different composition combinations particularly applicable to different situations can be produced. In addition, specific properties required for addressing a specific stenosis could be utilized to produce a tailor-made expander. (P. 3, L. 14-P. 4, L. 21))

Indeed, in discussing the method of coextrusion, the specification indicates expressly that an outer tensile layer/inner bonding layer is only an example (emphasis ours):

> More particularly with respect to the process, a tubular parison is first generated in a co-extrusion process whereby different polymeric materials are coaxially layered. Subsequently, the parison is inserted in a blow molding fixture, allowing the tube to be longitudinally drawn and radially expanded until the composite film is oriented, the maximum O.D. of the expander member is defined and a desired film thickness is achieved. For example, in forming the parison, PET of a predetermined viscosity may be coextruded with polyethylene where, forming the parison, the

> polyethylene lines the lumen thereof. When the expander member is formed from the parison in the blow molding operation, the PET layer affords the desired burst strength and limited radial expansion characteristic while the polyethylene layer enhances the ability to bond the resulting balloon to the catheter body. (P. 4, L. 22-35)

As a result, the specification does not limit the use of the PEEK and PEK to the outer tensile layer/inner bonding layer combination as the rejection reasons. Instead, the specification broadly conveys the idea of coextruded balloons using, for example, the polymers listed, such as PEEK and PEK in various combinations. It is submitted that the specification reasonably conveys the invention of the pending claims.

Allowance is requested.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 9/10/01

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